K123471

JUL 5 2013

HIOSSEN
Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date : October 10, 2012

1. Company and Correspondent making the submission:

| | |
|---|---|
| - Submitter's Name : | HiOSSEN Inc. |
| - Address : | 85 Ben Fairless Dr.<br>Fairless Hills PA 19030 |
| - Telephone No. | 888 678 0001 |
| - Contact : | Mr. Patrick Lim |

2. Device :

| | |
|---|---|
| Trade or (Proprietary) Name : | ETII SA Fixture System |
| Common or usual name : | Dental Implant |
| Classification Name : | Endosseous Dental Implant<br>21CFR872.3640<br>Class II<br>DZE |

3. Predicate Device :
The ET III SA FIXTURE SYSTEM, HIOSSEN Inc, K101096
The HGII Fixture system, HIOSSEN Inc, K090237
The HG II Short Fixture System, OSSTEM CO., LTD, K091678

4. Description :
1) The ETII SA Fixture System is dental implant made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. Fixture is made of pure titanium metal and supplied sterile. The surface is SA, Sandblasting and Acid etching, treated.

2) ETII SA Fixture is composed of single threads with internal hex connection straight body of bone level for two stage surgery. It has SA surface.
The ETII SA Fixture System is for single and two stage surgical procedures.

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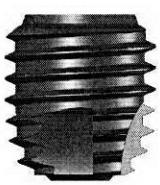
3) ETII SA Fixture System is compatibly used with abutment in the ET/SS Implant System (K120847)

4) The ETII SA Fixture System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

5) The ETII SA Fixture is available in various lengths and diameters according to the anatomical situation.

| diameter | lengths |
|---|---|
| 3.5mm | 8.7mm, 10.2mm, 11.7mm, 13.2mm, 15.2mm |
| 4.2mm | 7.2mm, 8.7mm, 10.2mm, 11.7mm, 13.2mm, 15.2mm |
| 4.45mm | 7.2mm, 8.7mm, 10.2mm, 11.7mm, 13.2mm, 15.2mm |
| 5.0mm | 6.2mm |
| 4.9mm | 7.2mm, 8.7mm, 10.2mm, 11.7mm, 13.2mm, 15.2mm |

**- Substantial Equivalence Matrix**

| | **ETII SA Fixture System** | **Predicate devices** | | |
|---|---|---|---|---|
| | | **ET III SA Fixture system** | **HGII Fixture system** | **HG II Short Fixture System** |
| **510(K) No.** | - | K101096 | K090237 | K091678 |
| **Manufacturer** | HIOSSEN Inc. | HIOSSEN Inc. | HIOSSEN Inc. | OSSTEM IMPLANT CO., LTD. |
| **Design** |  |  |  |  |
| **Intended Use** | The ETII SA Fixture system is indicated for use in partially or fully edentulous mandibles and maxillae, in support | ETIII SA Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support | The HG II Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or | The HG II Short Fixture System is intended for use in partially or fully edentulous mandibles and |

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| | | | | |
|---|---|---|---|---|
| | of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Ultra wide Fixture System is intended to be used in the molar region. | of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The ETIII SA Fixture System is for single and two stage surgical procedures. It is not for immediate load. The Ultra wide Fixture System is intended to be used in the molar region. | multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HG II Fixture System is for single and two stage surgical procedures. It is not for immediate load. | maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. It is not for immediate load. |
| **Structure** | - Straight body Type<br>-Self tapping<br>-Submerged fixture<br>- ETII SA Fixture System is for single and two stage surgical procedures. | -Taper body Type<br>-Self tapping<br>-Submerged fixture<br>- ETIII SA Fixture System is for single and two stage surgical procedures. | - Straight body Type<br>-Self tapping<br>-Submerged fixture | - Straight body Type<br>-Self tapping<br>-Submerged fixture |
| **Connection Type** | Internal hex connection | Internal hex connection | Internal hex connection | Internal hex connection |
| **Diameter (D)** | 3.5, 4.2, 4.45, 4.9, 5.0 | 3.75~5.05 | 3.5~4.85 | 4.85~6.85 |
| **Length (mm)** | 6.2, 7.2, 8.7, 10.2, 11.7, 13.2, 15.2 | 7.2~15.2 | 7.2~15.2 | 6.2 |
| **Material of Fixture** | Pure Titanium Grade 4 (ASTMF67-06) | Pure Titanium Grade 4 (ASTMF67-06) | Pure Titanium Grade 4 (ASTMF67-06) | Pure Titanium Grade 4 (ASTMF67-06) |
| **Surface** | SA | SA | RBM | RBM |
| **Sterilization** | Radiation Sterile | Radiation Sterile | Radiation Sterile | Radiation Sterile |
| **Shelf life** | 5 years | 5 years | 5 years | 5 years |
| **S E** | The ETII SA Fixture System has same material, indication for use and surface treatment as predicate device such as above and there are no big differences between design of ETII SA Fixture System and predicate device, especially ETII SA Fixture System is almost the same with HGII Fixture system except thread shape of the top | | | |

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5. Indication for use :
ETII SA Fixture system is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

6. Review :
The ETII SA Fixture System has same material and indication for use and similar design and technological characteristics as the predicate device.

The ETII SA Fixture System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing
Fatigue testing was considered according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the HGII Fixture and an angled abutment in support of the ETII SA Fixture.
ETII SA Fixture System has same material and similar design as the HGII Fixture.
Therefore, the fatigue test result of HGII Fixture can be used as a proof of ETII SA Fixture System

8. Summary of clinical testing
No clinical studies are submitted

9. Conclusions
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification HiOSSEN Inc. concludes that the ETII SA Fixture System is substantially equivalent to the predicate devices as described herein

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 5, 2013

Mr. Patrick Lim
Manager
Hiossen, Incorporated
85 Ben Fairless Drive
FAIRLESS HILLS PA 19030

Re: K123471
Trade/Device Name: ETII SA Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: May 10, 2013
Received: May 15, 2013

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lester W. Schultheis Jr
2013.07.05 12:40:24 -04'00'

Acting for
Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K 123471

Device Name : ETII SA Fixture System

Indication for use :
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Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Greene -S
2013.07.02 13:23:25 -04'00'
for M.Susan Runner, DDS, MA

**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** k123471